IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Cowley *et al.*	Art Unit	: 1656
Serial No.	: 10/501,411	Examiner	: Anand U. Desai
Filed	: July 12, 2004	Conf. No.	: 6101
Title	: MODIFICATION OF FEEDING BEHAVIOR USING PYY AND GLP-1		

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being electronically filed in accordance with § 1.6(a)(4) on the ___ day of _____, 2010.

_____
Allyson R. Hatton. Ph.D. Reg. No. 54,154

Commissioner for Patents

DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. JAMES TOBIN

I, James Tobin, a citizen of Ireland, residing in Newton, Massachusetts, hereby declare as follows:

1. I have been a research scientist at Pfizer (formerly, Wyeth), Cambridge, MA, since 1997. I am currently employed by Pfizer, the licensee of the above application, as Vice President and Chief Scientific Officer in the Biocorrection Research Unit. From 1990 to 1993, I was a postgraduate researcher at Harvard University. I received my Ph.D. in Biochemistry from Brandeis University in 1989. I have conducted molecular and biochemistry research for 25 years. A copy of my CV is attached.

2. I have reviewed and understand the contents of the present patent application.

3. I have been advised and understand that the Examiner has rejected at least claim 14 of the above-referenced application, which is directed to a method of decreasing calorie intake, food intake or appetite in a human subject in need thereof, which comprises peripherally administering prior to a meal to said subject PYY_{3-36} (peptide YY amino acids 3 to 36) from 5 to 100 nmoles per 70 to 75 kilogram body weight of the subject and a therapeutically effective amount of GLP-1 (glucagon-like peptide 1) or an agonist thereof, and where the peripheral

administration is by subcutaneous, intravenous, intramuscular, intranasal, transdermal, intraperitoneal, oral, topical, transmucosal, or sublingual administration or by pulmonary inhalation. I further have been advised and understand that the rejection is based, in part, on the Examiner's assertion that the specification does not reasonably provide enablement for the claimed method.

4. Studies performed by my collaborators and me showed that a peptide about the same size as PYY_{3-36} was efficacious in humans and rats following subcutaneous administration. The peptide, an oxyntomodulin ("OXM") analog, was administered to humans subcutaneously at dosages ranging from 200 to 800 µg flat dose (equivalent to 49.4 nmol to 197.6 nmol flat dose; and 2.7 to 10.7 µg/kg in a 75 kg human). The OXM analog was administered subcutaneously to rats at 4.3 µg/kg to 193 µg/kg (equivalent to 1.06 nmol/kg to 47.66 nmol/kg, which extrapolates to about 79.5 nmol to 3574.5 nmol per 75 kg human).

5. PYY_{3-36} is 33 amino acids and the OXM analog tested above is 37 amino acids in length. The proteins are therefore similar molecular weights. It is therefore reasonable to predict that PYY_{3-36} would be capable of having efficacy at similar dosages demonstrated by OXM following subcutaneous administration.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

DATE: 3 Feb 2010

James Tobin, Ph.D.

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